HEALTH INFORMATION designs

Texas HHSC DUR Board Meeting

Prospective Prior Authorization Proposals

October 22, 2021

Summary of Proposed Clinical Prior Authorizations

- Antifungals (topical)
  - New criteria
- Antipsychotic Agents
  - Add Lybalvi (olanzapine/samidorphan)
- Cytokine and CAM Antagonists
  - Add Enspryng (satralizumab-mwge)
- Lupus
  - New criteria
  - Benlysta (belimumab)
  - Lupkynis (voclosporin)
- SGLT2 Inhibitors
  - Criteria revision for Jardiance (empagliflozin)and Farxiga (dapagliflozin)

These classes were recommended for review by the MCOs and the Vendor Drug Program to ensure appropriate and safe utilization.

Topical Antifungals
Clinical Prior Authorization Proposal

Topical Antifungals for Onychomycosis

- Agents included in this edit:
  - Ciclopirox 8% solution
  - Jublia (efinaconazole) 10% solution
  - Kerydin (tavaborole) 5% solution
  - Approved for treatment of onychomycosis of the toenail in patients ≥ 6 years of age (efinaconazole and tavaborole) and patients ≥ 12 years of age (ciclopirox).
  - Recommended treatment course for efinaconazole and tavaborole is 48 weeks.
- WAC pricing[1]:
  - Jublia $644/4mL
  - Kerydin $604/4mL
  - Tavaborole $90/10mL

**Costs shown do not include any rebates that may be available.*

1. Jublia, Kerydin and Tavaborole. In: Red Book Online. Greenwood Village (CO): Truven Health Analytics; 2021 [cited 2021 Oct 22]. Available from www.micromedexsolutions.com.

Guidelines for the treatment of Onychomycosis

American Academy of Family Physicians (AAFP) (2013):

- Systemic antifungal agents are the most effective treatment for onychomycosis, but cure rates are much less than 100%. Terbinafine is the most effective systemic agent available (Grade C).
- When prescribing topical ciclopirox, patients should be informed that it has some benefit in the treatment of onychomycosis, but also has a high failure rate (Grade C).

Westerberg DP, Voyack MJ. Onychomycosis: Current Trends in Diagnosis and Treatment. Am Fam Physician 2013;88(11):762-770.

Topical Antifungal Agents for Onychomycosis Prior Authorization Proposal

Approval Criteria:

- Client has 180 days of therapy in the last 365 days **AND** has a diagnosis that compromises the immune system, **OR**
- Age ≥ 6 years for Jublia or Kerydin **OR** age ≥ 12 years for ciclopirox
- Diagnosis of onychomycosis of the toenail found in the last 730 days
- 12 weeks of treatment with an oral antifungal agent in the last 180 days, **OR** contraindication to oral therapy, **OR** client had a severe adverse reaction to oral therapy
- Diagnosis of active or chronic hepatic disease, lymphocytopenia or neutropenia found in the last 90 days
- Diagnosis of lupus found in the last 365 days

Lybalvi (olanzapine/samidorphan) Clinical Prior Authorization Proposal

Lybalvi (olanzapine/samidorphan)

- Lybalvi is indicated for the treatment of schizophrenia or bipolar I disorder in adults.
  - It is a combination of olanzapine (atypical antipsychotic) and samidorphan (opioid antagonist).
  - Recommended starting dose:
    - Schizophrenia: 5/10mg or 10/10mg daily
    - Bipolar I (manic or mixed episodes): 10/10mg or 15/10mg daily
    - Bipolar I (adjunct to lithium or valproate): 10/10mg daily
  - Maximum recommended dose:
    - 20/10mg daily
  - Note: may precipitate opioid withdrawal in patients who are dependent on opioids. Prior to initiating therapy, there should be at least a 7-day opioid-free interval from the last use of short-acting opioids and at least a 14-day opioid-free interval from the last use of long-acting opioids.
- WAC pricing[1]:
  - $1390 for30 tablets – all strengths

**Costs shown do not include any rebates that may be available.*

1. Lybalvi. In: Red Book Online. Greenwood Village (CO): Truven Health Analytics; 2021 [cited 2021 Oct 22]. Available from www.micromedexsolutions.com.

Lybalvi Clinical Prior Authorization Proposal

Approval Criteria:

- Note: will be added to current antipsychotic criteria
- If the request is the initial fill for an antipsychotic, the request will automatically approve for 90 days
- On subsequent fills:
  - Diagnosis of schizophrenia or bipolar I disorder found in the last 365 days
  - Diagnosis of opioid dependence not found in the last 365 days, **OR**, if diagnosis found, client has been opioid free for at least 14 days for long-acting opioids and 7 days for short-acting opioids
  - Client will not be taking more than 3 different antipsychotic agents concurrently

Enspryng (satralizumab-mwge)
Clinical Prior Authorization Proposal

Enspryng (satralizumab-mwge)

- Enpsryng is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adults who are anti-aquaporin-4 (AQP4) antibody positive.
  - Recommended dosing:
    - 120mg SQ weeks 0, 2 and 4, followed by 120mg SQ every 4 weeks (maintenance)
- WAC pricing[1]:
  - $14,615 for 120mg (1mL) injection

**Costs shown do not include any rebates that may be available.*

1. Enspryng. In: Red Book Online. Greenwood Village (CO): Truven Health Analytics; 2021 [cited 2021 Oct 22]. Available from www.micromedexsolutions.com.

Guidelines for the treatment of NMOSD

NMOSD (UpToDate) (2021):

- Long-term immunotherapy is indicated to reduce the risk of relapse as soon as the diagnosis of NMOSD is made. For those patients that are seropositive for AQP4 antibodies, treatment with eculizumab, inebilizumab or satralizumab is suggested over other immunosuppressive agents. (Grade 2C)
- For patients with acute or recurrent attacks of NMOSD, initial treatment with high-dose IV methylprednisolone (1 gram daily for 3 to 5 consecutive days) is suggested. (Grade 2C)
- For patients with severe symptoms unresponsive to glucocorticoids, treatment with plasma exchange is suggested. (Grade 2C)
- Immunosuppression is usually continued for at least 5 years for patients who are seropositive for AQP4, including those presenting with a single attack, because they are at high risk for relapse. However, optimal drug regimen and treatment duration for NMOSD are yet to be determined.

Glisson CC. Neuromyelitis optica spectrum disorders. In: UpToDate, Gonzalez-Scarano F (Ed), UpToDate, Waltham, MA. September 2021.

Enspryng Clinical PA Proposal

Approval Criteria:

- Client ≥ 18 years of age
- Diagnosis of NMOSD found in the last 730 days
- Will not have duplicate therapy
- No diagnosis of serious active infection found in the last 180 days
- Dose check [Manual]

Agents for Lupus
Clinical Prior Authorization Proposal

Agents for Lupus

- Agents included in this proposal:
  - Benlysta (belimumab) injection
  - Lupkynis (voclosporin) capsules
- Benlysta:
  - Indicated for patients 5 years of age and older with active, autoantibody-positive systemic lupus erythematosus (SLE) who are receiving standard therapy. Note: the subcutaneous formulation is only approved for administration in adult patients.
    - Dose is 200mg SQ once weekly.
  - Indicated for patients 18 years of age and older with active lupus nephritis who are receiving standard therapy.
    - Dose is 400mg SQ once weekly for 4 doses then 200mg SQ weekly thereafter.
- Lupkynis:
  - Indicated for patients 18 years of age and older with active lupus nephritis.
    - Recommended starting dose is 23.7mg orally twice a day and should be used in combination with mycophenolate mofetil and corticosteroids.
    - Initial starting dose for patients with severe renal impairment or mild/moderate hepatic impairment is 15.8mg twice a day.
    - If the patient has not seen therapeutic benefit by 24 weeks, provider should consider discontinuation of Lupkynis.
- WAC pricing[1]:
  - Benlysta: $3,983 for 4-200mg vials
  - Lupkynis: $11,850 for 180 capsules (30 days supply if dose is 23.7mg BID)

**Costs shown do not include any rebates that may be available.*

1. Benlysta, Lupkynis. In: Red Book Online. Greenwood Village (CO): Truven Health Analytics; 2021 [cited 2021 Oct 22]. Available from www.micromedexsolutions.

Benlysta Criteria Proposal

Approval Criteria:

- Client is ≥ 18 years of age
- Diagnosis of systemic lupus erythematosus (SLE) found in the last 730 days – must have laboratory confirmation of the presence of autoantibodies [Manual], OR
- Diagnosis of lupus nephritis (LN) found in the last 730 days
- Client is currently taking standard immunosuppressive therapy
- Client will not have concurrent therapy with a biologic DMARD agent
- Diagnosis of progressive multifocal leukoencephalopathy (PML) not found in the last 365 days
- Dose check
  - ≤ 200mg weekly for SLE
  - ≤ 400mg weekly for LN

Lupkynis Criteria Proposal

Approval Criteria:

- Client is ≥ 18 years of age
- Diagnosis of lupus nephritis (LN) found in the last 730 days
- Client is currently taking standard immunosuppressive therapy
- No claim for a strong CYP3A4 inhibitor found in the last 90 days
- Client is not currently taking cyclophosphamide
- Diagnosis of hypertensive emergency not found in the last 60 days
- Diagnosis of end stage renal disease (ESRD) not found in the last 365 days
- Dose check
  - ≤ 23.7mg twice daily
  - If client has severe renal impairment or mild/moderate hepatic impairment, dose ≤ 15.8 mg twice daily

SGLT2 Inhibitors
Clinical Prior Authorization Revision Proposal

SGLT2 Inhibitors

- Agents included in the proposed criteria revision:
  - Farxiga (dapagliflozin) – new indications added:
    - To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes (T2D) and either established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors.
    - To reduce the risk of CV death and hospitalization for heart failure (HF) in adults with HF with reduced ejection fraction (NYHA class II-IV).
    - To reduce the risk of sustained eGFR decline, end stage kidney disease, CF death and hospitalization for HF in adults with chronic kidney disease (CKD) at risk of progression.
  - Jardiance (empagliflozin) – new indications added:
    - To reduce the risk of CV death in adults with T2D and established CVD.
    - To reduce the risk of CV death plus hospitalization for heart failure in adults with HF and reduced ejection fraction.
- WAC pricing[1]:
  - Farxiga: $533 for 30 tablets
  - Jardiance: $549 for 30 tablets

**Costs shown do not include any rebates that may be available.*

1. Farxiga, Jardiance. In: Red Book Online. Greenwood Village (CO): Truven Health Analytics; 2021 [cited 2021 Oct 22]. Available from www.micromedexsolutions.

SGLT2 Inhibitors
Clinical PA Revision Proposal

Approval Criteria:

- Note: this class already has clinical PA criteria
- Current criteria:
  - Age check
  - Client is not on dialysis
  - Diagnosis of T2D
  - No diagnosis of severe renal impairment if request is for Farxiga
  - Dose check
- Recommended revision:
  - Diagnosis of heart failure found in the last 730 days, OR
  - For Farxiga, diagnosis of chronic kidney disease found in the last 730 days

Questions?